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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM12/1026

EXAMINER

DELACROIX MUIRHEI, C

ART UNIT

1614

PAPER NUMBER

12

**DATE MAILED:** 10/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

081966, 940

Attendant(s)

Tamar kin et al

Examiner

C. Delacoux-M

Group Art Unit

1614

 Responsive to communication(s) filed on 7/21/99. This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

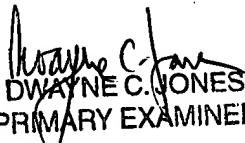
A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims** Claim(s) 1-32 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

 Claim(s) \_\_\_\_\_ is/are allowed. Claim(s) 1-32 is/are rejected. Claim(s) \_\_\_\_\_ is/are objected to. Claims \_\_\_\_\_ are subject to restriction or election requirement.**Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner. The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119** Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). All  Some\*  None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) \_\_\_\_\_. received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)** Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152  
DWAYNE C. JONES  
PRIMARY EXAMINER, 1614**-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --**

### **DETAILED ACTION**

1. Claims 1-3, 5, 6, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiosaka et al., 5,112,606.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Response to Amendment***

The following is responsive to Applicant's amendment received Jul. 21, 1999.

#### ***Status of the Claims***

No claims are cancelled. New claims 27-32 are added. Claims 1-32 are currently pending.

The previous rejection of claims 1-26 under 35 USC 102(b), set forth in paragraph 6 of the office action mailed March 17, 1999, is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous rejection of claims 9, 11, 13, 19, 21 under 35 USC 102(b) set forth in paragraph 5 of the office action mailed March 17, 1999, is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous rejection of claims 1-3, 5, 6, 8 under 35 USC 102(b), set forth in paragraph 5 of the office action mailed March 17, 1999 have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed March 17, 1999, with the following additional comment:

It is essentially Applicant's position that Shiosaka does not disclose Applicant's claimed compositions because the biologically active factors that are bound to the colloidal gold particles in Shiosaka are not released in vivo. This is contrary to Applicant's invention where the claimed compositions require the release of the factors from the colloidal metal.

Said arguments have been considered but are not found to be persuasive.

It is the Examiner's position that Applicant's argument concerning the eventual release of the biologically active factors from the colloidal gold in vivo does not distinguish the actual composition, structurally or physically, from the prior art composition. Said argument does not

negate the fact that Shiosaka discloses compositions comprising colloidal gold complexed with proteins and glucoproteins. The rejection is maintained.

*New Ground of Rejection*

*Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 9, 15, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheinberg 4,487,780.

Scheinberg discloses compositions comprising biologically active cysteine compounds in combination with gold or copper compounds. The compositions are administered to individuals for the purpose of treating rheumatoid arthritis. Please see the abstract; col. 3, lines 14-23.

4. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohmann et al.

Ohmann et al. teach the invention substantially as claimed. Ohmann discloses a composition comprising tumor necrosis factor- $\alpha$  (TNF) complexed with colloidal gold particles. Please see the abstract; page 44, Preparation of gold-ligand complexes.

*Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/02078 ('078) in view of Scheinberg, supra.

WO '078 discloses compositions comprising tumor necrosis factor- $\alpha$  (TNF) bound to a ligand that modulates the biological activity of the TNF by increasing the receptor binding activity and the cytotoxicity of TNF on tumor cells. The composition is used to treat tumors in individuals. Please see the abstract; page 7, lines 21-33; claims 23-26.

WO '078 does not disclose binding the TNF with colloidal metal such as silver or gold; however, the Examiner refers to Scheinberg which discloses compositions comprising biologically active cysteine compounds in combination with gold or copper compounds. The compositions are administered to individuals for the purpose of treating rheumatoid arthritis. Please see the abstract; col. 3, lines 14-23. Scheinberg discloses that the gold and silver particles serve to increase the efficacy of the cysteine compounds while lowering the dosage amount needed to treat rheumatoid arthritis. Please see col. 3, lines 14-23 and lines 66-68.

It would have been obvious to one of ordinary skill in the art to modify the method of WO '078 to administer compositions comprising TNF bound to colloidal gold or silver because such a modification would have been motivated the reasoned expectation of decreasing the dosage amount of TNF while at the same time increasing its efficacy in the treatment of tumors.

With respect to claim 11, vaccination of an individual in the prior art would have been obvious in view of the fact that the method steps of the claimed invention and that of the prior art are substantially similar.

Finally, concerning the use of adjuvants, pharmaceutically acceptable excipients or the use of additional known biologically active factors, these are art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to modify them in the prior art.

### ***Conclusion***

Claims 1-32 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM  
Oct. 25, 1999

DWAYNE C. JONES  
PRIMARY EXAMINER, 1614